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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,653	07/17/2000	Alexander V. Kabanov	UNMC-63117B	1205

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

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DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445653

Applicant(s)

KABANOV

Examiner

W E B M A N

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/22/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US Patent No. 5,410,016) in view of Ahmad et al. (US Patent No. 5,112,611) and Nakayama et al. (U.S. Patent No. 5,531,917) and Weiner et al. (U.S. Patent No. 5,171,737).

Hubbell et al. Teach block copolymers comprising a water-soluble region such as polylactic or polyamino acid (column 7, line 6 to column 8, line 68).

Controlled drug delivery of active agents such as enzymes from devices such as microspheres is disclosed (column 10, lines 29-48).

Hubbell et al. do not teach a charged surfactant.

Ahmad et al. teach papain for aiding human digestion (abstract).

Controlled release is disclosed (column 3, lines 7-11).

Nakayama et al. teach the stabilization of a proteolytic enzyme with a surfactant^{ta}₁ (abstract). Combinations of nonionic, anionic, and amphoteric surfactants are specified (column 2, line 62 bridging column 3, line 12). Papain is disclosed (column 3, lines 17-18). Sodium lauroyl sarcosinate and lauryl dimethylaminoacetic betaine are specified (column 5 and 6, Table 1).

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Weiner et al. teach dioleoyl phosphatidylethanolamine (DOPE) and dioleoyl phosphatidycholine (DOPC) as surfactants used for delivery of bioactive agents (abstract, column 2, lines 28-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to deliver papain with the device of Hubbell et al to achieve the beneficial effect of aiding human digestion in view of Ahmad et al. and to add surfactants to achieve the beneficial effect of stabilizing the enzyme in view of Nakayama et al.

As to the claimed complex, it is argued that such is inherently formed during mixing of the components to make the obvious composition. As to the particular claimed polyanionic and polycationic segments of the claimed block copolymer, polyaspartic acid and polylysine are well known in the art as commercially available polyamino acids for the Hubbell et al. biodegradable region.

As to the claimed nonionic surfactants, one of ordinary skill would use DOPE or DOPC as such because of their utility for delivering bioactive agents in view of Wiener et al.

As to the claims weight percent, it is within the skill in the art to select optimal parameters such as ratios or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Therefore, the ratios or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

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Applicants argue that the Hubbell polymers are not block copolymers but rather polymerized and crosslinked macromers. However, those macromers are block copolymers. Applicants do not exclude crosslinked block copolymers.

Applicants argue hindsight, nothing that Hubbell et al does not teach the oral administration of papain taught by Ahmad et al. However, Hubbell et al do teach microspheres for control release which vehicles are well-known in the pharmaceutical art to be delivered orally in capsules. Applicants argue that the references are drawn from totally unrelated fields. However, they all concern vehicles containing bioactive agents. Applicants argue that Hubbell et al is combined with more than one reference. However, combination with multiple references is entirely proper. Applicants argue that Nakayama et al concerns the inactivating effect of water, which is not a problem in Hubbell et al. However, Hubbell et al teaches encapsulation using an aqueous mixture (column 10, lines 41-43). Applicants argue that there is no rational basis for combining Weiner et al with Hubbell et al because Weiner et al concerns oil in water emulsions, However, Hubbell et al teach formation of microspheres in such an emulsion (column 10, lines 43-47). Thus, contrary to applicants' assertion of hindsight, motivation to combine is provided.

Applicants, further argue that the nonionic surfactants of Nakayama et al do not meet the requirement of claim 1 for a surfactant oppositely charged to the block copolymer. However, Nakayama et al, as cited in the rejected ^{ion}, teaches mixtures of charged and uncharged surfactants. More particularly, applicants argue that Nakayama et al do not teach cationic surfactants required for the anionic polymer of claim 5.

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However, Nakayama et al teach amphoteric surfactants, as cited in the rejection.

The cited betaine possesses a positive charge. The cited sarcosinate at physiological pH also contains a ^{ve}positively charge. Thus, the Nakayama et al mixture of surfactants necessarily possesses the claimed surfactants.

Lastly, applicants distinguish over In re Boesh because the references were not combined using hindsight. However, Here, there is motivation to combine. Therefore, there is no hindsight. Thus, In re Boesch applies.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 308-0570. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR
November 6, 2002



EDWARD J. WEBMAN
PRINCIPAL EXAMINER
GROUP 1500